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Comparison of text-messaging to voice telephone interviews for active surveillance of adverse events following immunisation

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Abstract

Objectives: In 2013, the Follow-up and Active Surveillance of Trivalent Influenza Vaccine in Mums (FASTMum) program began using short message service (SMS) to collect adverse event information in pregnant women who recently received trivalent influenza vaccine (TIV). This study was designed to compare data collected via SMS and telephone for the purposes of monitoring vaccine safety.

Methods: 344 women who received TIV were randomly assigned to a telephone interview group. They were telephoned seven days post-vaccination and administered a standard survey soliciting any adverse events following immunisation (AEFI) they experienced. They were matched by brand of vaccine, age group, and residence to 344 women who were sent a SMS seven days post-vaccination. The SMS solicited similar information. AEFI reported by SMS and telephone interview were compared by calculating risk ratios.

Results: Response rate was higher to SMS compared to telephone interview (90.1% vs. 63.9%). Women who were surveyed by SMS were significantly less likely to report an AEFI compared to women who were surveyed by telephone (RR: 0.41; 95% CI: 0.29-0.59). The greatest discrepancies between SMS and telephone interview were for self-reported injection site reactions (3.1% vs. 16.8%) and unsolicited (or “other”) events (11.4% vs. 4.1%). Data collected by SMS was significantly timelier.

Conclusions: Data collection by SMS results in significantly improved response rates and timeliness of vaccine safety data. Systems which incorporate SMS could be used to more rapidly detect safety signals and promote more rapid public health response to vaccine quality issues.

Keywords: vaccination; public health surveillance; text messaging; influenza vaccine

1. Introduction

Vaccine safety programs are fundamental for promoting vaccine uptake in the community, since any perceived vaccine safety issue can undermine confidence in vaccination [1]. Misperceptions of vaccine safety are a common contributor to low immunisation rates [2-6]. For example, in Western Australia an unexpected spike in adverse events following trivalent influenza vaccination in children in 2010 resulted in an 84% reduction in influenza vaccine uptake in young children [7, 8]. This example serves as a reminder of the necessity of vigilant vaccine safety programs and the importance of rapid signal response. Further, influenza vaccines continually change in antigenic composition to accommodate shifting strains, but are not considered new vaccines and do not undergo the same efficacy and safety studies as new vaccines [9]. Timely collection of vaccine safety data is necessary in order to identify early warning signals and ensure vaccine quality.

Some vaccine safety surveillance programs incorporate short message service (SMS) communication to monitor adverse events following immunisation (AEFI) details in near real-time [10-13]. While such methods offer rapid data collection and dissemination of results, to date, no study has investigated the potential differences between SMS and telephone interview data collection methods. This study compares SMS with telephone interviews for the purpose of performing vaccine safety surveillance in terms of a) response rate; b) adverse events reported; and c) the timeliness of obtaining data.

2. Methods

The Follow-up and Active Surveillance of Trivalent influenza vaccine in Mums (FASTMum) program has monitored the safety of pregnant women who receive inactivated TIV in Western Australia since 2012 [14]. Historically, data collection has relied on telephone interviews of vaccinated pregnant women; however, in 2013, SMS was introduced as a method of collecting AEFI information [11]. In 2014, a subset of 344 women were followed up by telephone

interview for comparison purposes. All follow-up occurred between 16 March and 22 May 2014.

2.1 Sample selection

In Western Australia, immunisation providers report details of antenatal influenza immunisations to the Western Australia Department of Health (WA Health) by submitting immunisation reports which include the vaccination date, vaccine brand and batch number, and mobile phone number of the vaccinee [11]. At the time of vaccination, women are asked to indicate on these reports whether they give permission to be contacted by telephone or SMS by WA Health for the purposes of monitoring vaccine safety [11]. During the study time period, 2,011 women were reported to WA Health as receiving TIV and consented to follow-up. A random sample of women (n=344) was selected to receive a telephone interview seven days post-vaccination using a random number generator. The remaining 1,667 women were followed up by SMS seven days post-vaccination. Of these 1,667 women, 344 were individually matched by brand of TIV received, age group (18-29 years, 30-39 years, or 40-45 years), and residence (metropolitan or rural) to a sample of women who received the same questions via SMS. The sample size was powered to detect a ±4% difference between groups at β=.80.

2.2 Data collection

For participants in the SMS-group, a text message was sent seven days following vaccination asking:

> "In the week since your vaccination, did you experience any reaction, fever, or illness? Please reply Y or N."

Women who did not reply were sent a second message within 24 hours with the same text. Women who replied "yes" to either message were sent an additional SMS asking them to complete a five minute survey on their mobile phone. Women who did not complete the survey were telephoned to ask about details related to their reaction. The survey asked if

they had experienced any of the following: fever, headache, fatigue, rash, swelling, redness, or pain at the injection site, rigors, or convulsions. Women could make multiple selections and were permitted to record additional events in a free text field. At the end of the survey, women were asked if they had visited any doctor, medical centre, after hours clinic, or emergency department regarding their reaction.

For participants in the telephone-group, a research nurse telephoned the mobile phone of the participant seven days post-vaccination. No SMS messages were sent to women in this group, and all questions in the telephone interview were identical to those of the mobile phone survey. Women were asked by telephone whether they experienced any reaction and women who replied affirmatively were asked about details related to the reaction. Women who did not respond to telephone interview were telephoned again 24 hours later, until a maximum of three contact attempts were made.

2.4 Outcomes measured

We were interested in comparing the two methods of collecting vaccine safety data in terms of response rate, reactions reported, and timeliness of the data collection. We defined 'response rate' as the proportion of participants who returned a text message in the SMS-group or answered a telephone call in the telephone-group. The proportion of women who experienced each reaction included on the surveys was calculated and compared between groups. We also compared response rate to SMS and telephone interview by sociodemographic characteristics. We calculated the time required to collect completed adverse event information for both data collection methods.

2.5 Statistical analysis

Data were analysed using SAS version 9.3 (SAS Institute Inc, Sydney, NSW, Australia). Response rates to SMS and telephone interview were compared by sociodemographic subgroups using Cochran Mantel-Haenszel (CMH) chi square tests. The response rates to

SMS versus telephone interview were compared overall and by sociodemographic factors by calculating risk ratios (α=.05). Risk ratios were also used to compare the number of women who reported each event by SMS and telephone interview. Independent sample t-tests were used to compare the mean time (in days) required to collect complete AEFI data by SMS and telephone interview.

3 Results

A total of 688 women who had received trivalent influenza vaccine between 9 March and 15 May 2014 were followed up: 344 by SMS and 344 by telephone interview (Figure 1). The majority of women resided in the metropolitan area (84.6%), were non-Aboriginal (95.8%), were in their second or third trimester of pregnancy (80.0%), were between 30 and 45 years of age (62.2%) and were in the top 60% of socioeconomic levels (86.1%). Women commonly received either Vaxigrip® (40.7%) or Fluvax® (49.1%); 8.3% received Fluarix®, and 1.9% received other brands. There were no demographic or vaccination differences identified between SMS and telephone groups ($p>0.05$).

3.1 Response Rate

A total of 310 (90.1%) of women replied to SMS (Figure 1). Response to SMS was lower in Aboriginal women compared to non-Aboriginal women (66.7% vs. 92.2%; CMH=9.22, $p<0.01$). No difference was observed in response to SMS by residence, trimester of pregnancy, socioeconomic status, or age group ($p<0.05$). A total of 220 (66.7%) of women responded to telephone interview. Response to telephone was significantly lower in women who resided outside the metropolitan area compared to those within the metropolitan area (78.5% vs. 88.3%; CMH: 7.06, $p<0.01$). No difference was observed in response to telephone interview by Aboriginal status, trimester of pregnancy, socioeconomic status, or age group ($p>0.05$).

Overall, response rate was significantly higher with SMS than telephone interviews (90.1% vs 66.7%, p<0.01)(Table 1). Women were 40% more likely to reply to SMS compared to telephone interview (RR: 1.41, 95% CI: 1.29-1.54). This association was consistent across sociodemographic groups, with the exception of Aboriginal women, women aged 40-45 years and women in the second quintile of socioeconomic status (*p*>0.05).

On average, 1.4 telephone calls were required to complete a telephone interview with one woman; 146 (66.4%) of women replied to the first telephone call. The majority of women who replied to SMS, replied to the first message (n=277, 89.3%). Of the 38 women who replied to the SMS indicating they had experienced an AEFI, 23 (60.5%) women provided information related to the event: 10 (43.5%) by mobile phone survey and 13 (56.5%) had to be telephoned. The remaining 15 women who indicated they experienced a reaction could not be reached by either telephone interview or SMS.

3.2 Events reported

Women in the SMS-group were 59% less likely to report an AEFI compared to women in the telephone-group (RR 0.41; 95% CI 0.29-0.59) (Table 2). When we compared the events reported by women who experienced an AEFI, women in the SMS-group were 81% less likely (RR 0.18, 95% CI 0.09-0.37) to report a local reaction and 64% less likely (RR: 0.36, 95% CI 0.05-0.70) to report events not included in the survey (Table 2). Women were just as likely to report fever, headache, fatigue, vomiting, rash, or rigors by SMS or telephone, and no women reported convulsions. Women were just as likely to report having sought medical care for their AEFI by SMS and telephone (RR: 0.45; 95% CI: 0.11-1.85).

3.3 Timeliness of data

Collection of AEFI details from SMS participants required significantly less time than telephone participants (Figure 2); 95.6% of women in the SMS-group reported complete AEFI details within 24 hours of follow-up, compared to 16.6% of women in the telephone-

group. On average, complete AEFI information was obtained from women in the SMS-group within 2.4 hours (95% CI: 2.4-4.8 hours) of follow-up, whereas information was obtained from women in the telephone-group within 2.7 days (95% CI: 2.5-3.0 days)(t: 20.3, p<0.01). The time required to collect information was similar for women who experienced a reaction as those who did not experience a reaction (1.6 days vs 1.3 days, t: -1.03, p=0.30).

4 Discussion

To our knowledge, this is the first study specifically designed to directly compare SMS with telephone interview for the purpose of AEFI surveillance. Based on our results, an SMS-based adverse event monitoring program would detect a similar rate of medically-attended adverse events as a telephone-based system. Data collection by SMS was significantly more rapid and associated with improved response rates over telephone interviews. These results indicate SMS could be used to implement an AEFI monitoring program with the capability for rapid response to safety signals.

Previous observational studies support our findings, in that response to SMS often exceeds 80% [10, 11] and adverse event information can vary when collected by SMS and telephone interview, which is consistent with previous observational studies [11]. Internationally, there is growing evidence supporting the feasibility of SMS as a method of data collection. In the United States, researchers successfully used SMS to monitor the reactogenicity of trivalent influenza vaccine in children over a seven day period [15]. In Sweden, Bexelius et al. [16] compared SMS to standardised telephone interviews for administering three survey questions related to influenza and influenza vaccination. Vaccination data collected by SMS was statistically similar to data collected by telephone interview. A number of other public health systems have further demonstrated the utility of SMS for data collection, including collection of immunisation status [16], asthma symptoms [17], irritable bowel syndrome symptoms [18], Ebolavirus symptoms [19], and pain outcomes [20].

Our results indicate that SMS can be used as a valuable tool for signal detection; however, some of our findings suggest there are limitations of SMS for AEFI monitoring. First, although 90% of women replied to the initial SMS, 56.5% of women who reported an AEFI via SMS did not respond to the follow-up SMS and had to be telephoned to collect details of the event. These results indicate SMS may not be a complete solution to AEFI information collection. Second, there were some distinct differences in the events reported by SMS compared to telephone. Women surveyed by telephone were more likely to report any adverse event, which can largely be attributed to their increased reporting of injection site reactions. Although not designed to compare the different methods of AEFI data collection, a similar previous investigation found that women followed up by telephone interview were four times as likely to report a local reaction and nearly twice as likely to report a systemic reaction [11], similar to our results. These findings may suggest that SMS is not suitable for determining an accurate proportion of vaccinees who experience mild, common events, but would instead be suited for monitoring for changes in the safety profile of a vaccine. Regardless of these shortfalls, SMS would detect a safety signal more rapidly compared to telephone interviews.

While this study provides valuable information which can be used to improve vaccine safety monitoring programs, there were several limitations to our investigation. Due to the population of the routine vaccine safety monitoring program in Western Australia, our sample was restricted to pregnant females and our results may not necessarily apply to other demographic groups. The events reported in this study were self-reported and had not been verified by a health professional. Discrepancies between the rates of AEFI reported by SMS and by telephone interview may be due to response bias. It is plausible that the method of inquiry affected the probability for a vaccinee to recall and report an AEFI. Additional research where reported AEFI are medically verified could provide further information on the use of SMS for data collection. Finally, unlike the SMS group, only 17% of the telephone group were successfully contacted at seven days post-vaccination. As a result, the variation

in time required to follow-up by telephone compared to SMS may have biased our results. However, among the women who were successfully contacted by telephone within seven days, 37% reported a reaction, similar to the proportion of all women who were followed up by telephone interview. This indicates that variation in follow-up time is unlikely to be the reason for the differences in AEFI observed in our study.

4.1 Conclusions

We compared the use of SMS and telephone interviews for the purposes of collecting AEFI information. Our results show that SMS can be used to improve existing vaccine safety surveillance systems, with certain caveats. Evaluations such as ours are important for informing public health initiatives, considering the current interest in transitioning surveillance systems to mobile phone technology [10-12, 18, 19]. Systems which incorporate SMS as a method of data collection have the potential to more rapidly detect a safety signals and facilitate quick response to identified vaccine quality issues and warrant further exploration.

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Figure 1 title:

Figure 1. Adverse event following influenza immunisation monitoring by SMS and telephone – Western Australia, Australia, March-May, 2014.

Figure 1 footnotes:

SMS, short message service

Figure 2 title:

Figure 2. Number of follow-up days, by method of adverse event reporting – Western Australia, Australia, March – May, 2014.

Figure 2 footnotes:

SMS, short message service

AEFI, adverse event following immunisation

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